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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/615,814	03/14/96	JOHNSON	B C348.12-0011

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33M1/0213

EXAMINER

ASHER, K

ART UNIT

PAPER NUMBER

3312

8

DATE MAILED: 02/13/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 2/11/97
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1-22 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-22 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413; 9-sheets of In re Schneller guidance.
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

file copy

5

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10 **THE MAIL DATE OF THIS OFFICE ACTION RESTARTS THE 3 MONTH SSP SET IN THE FINAL REJECTION OF 1/27/97. THIS IS A SUPPLEMENTAL FINAL REJECTION.**

15 Claims 1-22 are rejected under the judicially created doctrine of double patenting over the claims of copending patent numbers 5533499, 5533503, 5549103, and 5476091. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as is clearly seen by comparison of the claims. Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP 804.

25

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

30 *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

35 *The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.*

40 The original disclosure is limited to a nasal dilator only. The disclosure is not generic to dilators for all human anatomy. In other words, applicant has only disclosed the subset of a nasal dilator from the possible set of dilators for all human anatomy. It is noted that this case purports to be a CON of 08/183,916. Yet the

recitation of claim 8 for a human anatomy dilator is drawn to the subject matter of patent # 5476091, which was a CIP of the same 08/183,916.

5 *Claim 8 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.*

10 *Claims 8, 9, 11, 13, 17, 20, and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over Sawyer.*

Sawyer teaches applicant's device as is broadly recited in claim 8 by the unit truss (figure 2) which comprises a resilient member and first and second end regions 5/6 which dilate the nose by the restoring force of the spring/resilient member. With regard to the recitation of a normally planar state, no difference is seen between this and the teachings of Sawyer to bend the device contrary to its natural state so as to generate a restoring force (page 1, column 2). Note the lack of adhesive between end regions 5/6. The recitation of release liners to cover the adhesive members would have been obvious to one of ordinary skill in the art given the plethora of such arrangement sin almost all arts. The substitution of one known spring material for another would also have been would have been obvious to one of ordinary skill in the art, especially given the teachings of Sawyer in page 1, lines 68+. It would have been obvious to one of ordinary skill in the art at the time the invention was made as the simple evolution of the 1919 Sawyer device.

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Claims 10, 12, 14-16, 18, 19, and 21 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112, to include all of the limitations of the base claim and any intervening claims; IF THEY ARE OF SCOPE DIFFERENT THAN THAT GRANTED IN THE PREVIOUS CASES, AND IF AN ACCEPTABLE TERMINAL DISCLAIMER IS FILED.

5

Claims 1-7 would be allowable over the prior art of record, IF THEY ARE OF SCOPE DIFFERENT THAN THAT GRANTED IN THE PREVIOUS CASES, AND IF AN ACCEPTABLE TERMINAL DISCLAIMER IS FILED.

10

Applicant's arguments and Rule 1.132 Affidavit filed 11/12/1996, have been fully considered but they are not deemed to be persuasive.

15

Applicant's affidavit is insufficient to overcome the rejection of claims 8, 9, 11, 13, 17, 20, and 22 because there is no nexus between the subject matter claimed here and that described as providing the commercial success. Specifically, applicant's affidavit relies on the provision of the resilient band springs in combination with the planar truss. The resilient band springs are not recited in claims 8, 9, 11, 13, 17, 20, and 22. Applicant's arguments directed to their interpretation of In re Schneller are not persuasive because the open claim terminology in both the instant application and the patents cited does extend the coverage granted in the patents. This is the point of a double patenting rejection based upon In re Schneller. Applicant's request for additional clarification of In re Schneller double patenting during the telephone interview of 2/11/97 has been noted. Please see attached sheets - 9 sheets, which comprise the guidance given to the Corps on this matter. Applicant's earlier patents disclose everything disclosed in the instant application, disregarding the New Matter rejection in the instant application. Therefore the answer to question # 1 is Yes.

Further there was no reason why applicant was prevented from presenting the instant claims in the earlier patents. I.e. the answer to question # 2 is also Yes. Therefore, statutory, non-obvious type double patenting is proper in the instant application. Put another way, applicant's presentation of broader claims in the instant application attempts to extend the coverage of the narrower claims in the earlier patents, and therefore is fair game for double patenting. A Terminal Disclaimer directed to each of the four patents the Examiner based the statutory, non-obvious type double patenting rejection on is required to overcome the same. Applicant's arguments directed to the new matter rejection are not persuasive because applicant's original disclosure fails to provide support for the breadth of claim 8. According to 5 applicant's arguments he could claim a wound dilator, a mouth dilator, a wrinkle dilator, etc. This is clearly erroneous. All that applicant disclosed in his original application was a nasal dilator. That was all that was described, discussed or illustrated. Every time the word "dilator" appears in the original disclosure, it is preceded by "nasal". Applicant is not entitled to coverage of anything but a nasal 10 dilator. Applicant's "inherency" arguments are completely non-persuasive because applicant has failed to prove that his nasal dilator could function as a dilator for any human tissue. Further, applicant's excessively broad language in claim 8 would not distinguish over the wrinkle smoothing patent cited in one of the parent applications. 15 Applicant's arguments directed to "unitary" is also completely non-persuasive and is 20

contradicted by his own 132 Affidavit where he discusses selling 150,000,000 units.

If the device of Appendix A is a "unit", so is the Sawyer device. Clearly applicant's device also requires "assembly" before being sold. Applicant's arguments directed to differences between applicant's truss and the truss of Sawyer are not persuasive

5 because applicant is relying on conclusions as to "uniform restoring force" and "the natural bent state" of Sawyer. Further, applicant's arguments are not consistent in scope with the shear breadth of his independent claim 8. Applicant's arguments bridging pages 8 and 9 of the 11/12/1996 response are also not persuasive with regard to claim 8 because Sawyer teaches the structure recited in claim 8, i.e. " a dilator", "

10 a truss of a single body" (wire 7) with spaced apart end surfaces, and "engagement means" at said end surfaces (the bent portions of Sawyer's wire 7 at 8 and 9). The difference being that the engagement means of Sawyer (pads or cups, 5/10) are attached mechanically vs. adhesively as is recognized in the rejection of these claims.

15 Applicant's final arguments directed to the advantage of adhesively attaching the truss to the user's nose being an improvement over Sawyer, allegedly evidenced by

applicant's competitors, is not persuasive because again because applicant's arguments are not consistent in scope with his claim language. Claim 8 does not require that the truss be adhesively attached all along its underside to the wearer's nose. The

20 Terminal Disclaimer filed 11/12/1996 is defective because 1) no documentary evidence of a chain of title from the original inventor(s) to assignee has been

submitted, nor is the reel and frame number specified as to where such evidence is recorded in the Office; 2) no statement specifying that the evidentiary documents have been reviewed and that, to the best of the assignee's knowledge and belief title is in the assignee seeking to take action; and 3) does not cover all of the patents the double patenting rejections are based upon. The fax of 2/7/97 providing these missing portions of the Terminal Disclaimer have been forwarded to the paralegal, Mr. Andre Robinson, for review. A separate letter will be sent addressing the Terminal Disclaimer.

10 *THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).*

15 *A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.*

20
25 *Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner K. L. Asher at telephone number (703) 308-0858.*

30 *Any inquiry of a general nature should be directed to the Group receptionist at (703) 308-0858.*

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Status inquiries are to be handled according to MPEP section 203, and directed to the Group receptionist, not the Examiner.

5 *Inquiries as to Terminal Disclaimer and PCT requirements should be directed to the Group Paralegal, Mr. Andre Robinson, at (703) 308-2104.*

*The facsimile phone number for Art Unit 3312 is (703) 308 - 3139. **PLEASE CALL THE EXAMINER PRIOR TO SENDING ANY FAX.** This will ensure that the Examiner receives the fax promptly.*

10

February 12, 1997


KIMBERLY L. ASHER
PRIMARY EXAMINER
GROUP 3300

Attachment to Supplemental FR 8/21/2/97

#10

~~determination should always be applied [the administratively simple solution], the Board of Patent Appeals and Interferences has concluded that use of a two-way obviousness analysis is not always required to support an obvious-type double patenting rejection. Ex parte Nesbit, 25 USPQ2d 181 (Bd. Pat. App. & Int. 1992).~~

~~When making a two-way obviousness determination where appropriate, it is necessary to apply the Graham obviousness analysis twice, once with the application claims as the claims in issue, and once with the patent claims as the claims in issue. Where a two-way obviousness determination is required, an obvious-type double patenting rejection is appropriate only where each analysis compels a conclusion that the invention defined in the claims in issue is an obvious variation of the invention defined in a claim in the other application/patent. If either analysis does not compel a conclusion of obviousness, no double patenting rejection of the obvious-type is made, but this does not necessarily preclude a rejection based on non-statutory double patenting (note c below).~~

c. Nonobviousness

There are some unique circumstances where it has been recognized that another type of non-statutory double patenting is applicable even where the inventions claimed in two or more applications/patents are considered nonobvious over each other. These circumstances are illustrated by the facts before the court in In re Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

Schneller disclosed an invention relating to a wire clip having three elements known in the prior art (A, B, and C), and two features (X and Y) which he had invented that could be used separately or in combination. Schneller acknowledged the best mode of his invention used the two features (X and Y) in combination. The claims of the patent were directed to a wire clip comprising ABCX. Schneller voluntarily filed a divisional application claiming wire clips comprising ABCY and ABCXY. Without determining that the combinations ABCY and ABCXY were obvious over the combination ABCX claimed in the patent, the court affirmed the double patenting rejection. It was observed that the claims in both the patent and the application cover the preferred embodiment disclosed in both the application and the patent (ABCXY). Since patent protection for the metal clips defined by ABCXY, fully disclosed in and covered by the claims of the patent, would be extended by allowance of the appealed claims, the double patenting rejection was affirmed.

In making an analysis for this type of non-statutory double patenting, the first question is: Is the subject matter recited in the claims of the application fully disclosed in the patent and covered by a claim in the patent? If the answer is no - double patenting does not exist. If the answer is yes, the second question is: Whether there is any reason why applicant was prevented from presenting the same claims for examination in the

issued patent? If the answer is no, a double patenting rejection is appropriate because, as stated in Schneller:

. . . even a minimum concern for the public interest requires an applicant to establish that the inventions are in fact independent and distinct and hence that the grant of a patent on the later application will not result in a timewise extension of the protection afforded by his earlier patent. Failing in this, an applicant's remedy lies in filing a terminal disclaimer which will effectively prevent his result.

and further:

Under the circumstances of the instant case, wherein we find no valid excuse or mitigating circumstances making it either reasonable or equitable to make an exception, and wherein there is no terminal disclaimer, the rule against "double patenting" must be applied.

A fact situation similar to that in Schneller was presented to a Federal Circuit panel in In re Kaplan, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986). Kaplan had been issued a patent on a process of making chemicals in the presence of an organic solvent. Among the organic solvents disclosed and claimed as being useful were tetraglyme and sulfolane. One unclaimed example in the patent was specifically directed to a mixture of these two solvents. The claims in the application to Kaplan and Walker, the application before the Office, were directed to essentially the same chemical process, but requiring the use of the solvent mixture of tetraglyme and sulfolane. In reversing the double patenting rejection, the court stated that the mere fact that the broad process claim of the patent requiring an organic solvent reads on or "dominates" the narrower claim directed to basically the same process using a specific solvent mixture does not, per se, justify a double patenting rejection. The court also pointed out that the double patenting rejection improperly used the disclosure of the joint invention (solvent mixture) in the Kaplan patent specification as though it were prior art.

A significant factor in the Kaplan case was that the broad invention was invented by Kaplan, and the narrow invention (i.e., using a specific combination of solvents) was invented by Kaplan and Walker. Since these applications (as the applications in Braat) were filed before the Patent Law Amendments Act of 1984 (Pub. Law 98-622, § 104, November 8, 1984) amending § 116 to expressly authorize filing a patent application in the names of joint inventors which did not necessarily make a contribution to the invention defined in each claim in the patent, it was necessary to file multiple applications to claim both the broad and narrow inventions. Accordingly, there was a valid reason why the claims to the specific solvent mixture were not presented for

examination in the Kaplan patent application.

Recently, the Court held that when a patentee voluntarily elects to file a continuing application to prosecute the broad genus claims, in order to obtain an allowance of a narrow species claim, the species claim precludes issuance of the generic application, absent a terminal disclaimer. In re Goodman, 29 USPQ 2d 2010 (Fed. Cir. 1993). In Goodman, the specifications of the patent and the application disclosed the invention in general terms, but provided a single working example; i.e., a method of producing gamma-interferon using a DNA construct comprising an expression cassette with expression regulatory elements functional in tobacco plants (a dicotyledonous plant) and a structural gene coding for gamma-interferon. The claims the Court considered as presenting a double patenting issue were the narrow species claims in the allowed patent directed to a DNA construct comprising expression regulatory elements derived from a specific type of plasmid and which were functional in dicotyledonous plant cells and a structural gene encoding gamma-interferon and, the claims in the application directed to a DNA construct with expression regulatory elements functional in any plant cell and a structural gene coding for any interferon. The Court held that this type of situation did not require a "two-way" analysis because P.T.O. actions did not dictate the rate of prosecution. The patentee had the opportunity to file an immediate appeal to the courts on the genus, but instead he adopted an easier course of action by filing a continuation application on the broad claims and obtaining issuance of the narrow genus. Although the filing dates of the patent and application were identical, the Court found that this type of situation was sufficiently analogous to a rejection under 35 U.S.C. §102 wherein an earlier species disclosure defeats any generic claim. Cf. Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985). Accordingly, the Court held that a terminal disclaimer was necessary in order to prevent the patentee from gaining an unjust extension of the 17-year term on a species application when the broad genus was issued at a later date.

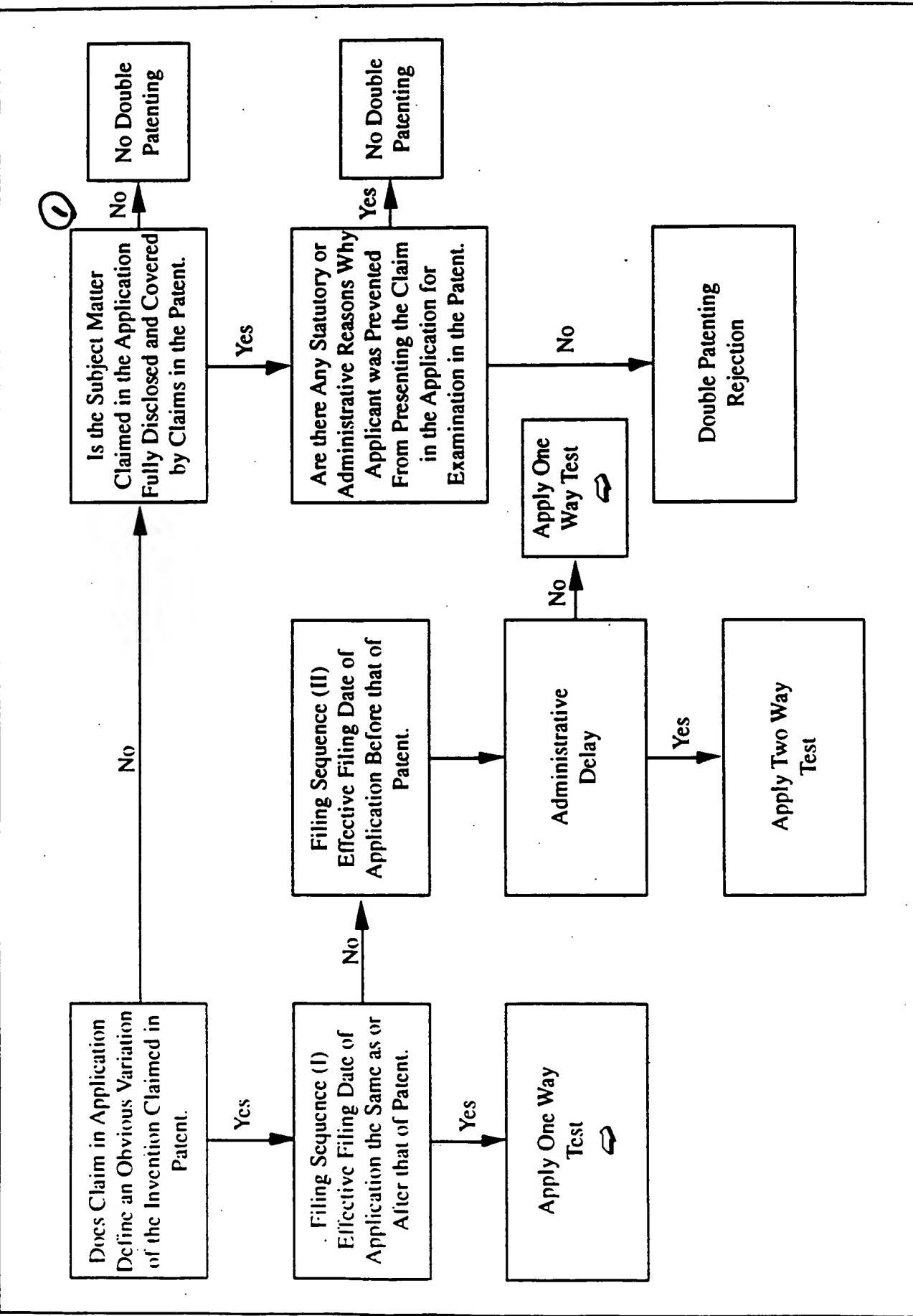
Each double patenting situation has to be decided on its own facts. To the extent that one would view the Schneller and Kaplan decisions to be in conflict, it is clear that Schneller is the controlling precedent. Decisions of a three-judge panel cannot overturn prior precedential decisions. See UMC Elec. Co. v. United States, 816 F.2d 647, n.6, 2 USPQ2d 1465, n.6 (Fed. Cir. 1987), cert. denied, 484 U.S. 1025 (1988).

Unlike statutory double patenting (§ 101), a double patenting rejection based on any non-statutory ground can be overcome by an appropriate terminal disclaimer.

4. Design/plant-utility situations

Double patenting issues may be raised where an applicant has filed both an utility patent application (35 U.S.C. § 111) and

Non-Statutory/Double Patenting



Asher

① COVERED BY CLAIMS IN THE PATENT MEANS THAT THE CLAIMS ON THE PATENT AND THE CLAIMS IN THE APPLICATION GIVES PROTECTION TO COMMON SUBJECT MATTER.

EXAMPLE V

This example deals with non-statutory double patenting that also is non-obvious (In re Schneller).

FACT SITUATION

An earlier filed patent specifically discloses a device comprising a combination of a variety elements (A, B, C, X, and Y) wherein there are three disclosed embodiments

- (1) A B C X — CIP
(2) A B C Y
(3) A B C X Y — CIP
- X = CIP subject matter

The claim in this patent reads as follows:

Patent Claim 1: A device comprising the combination of elements A, B, C, and X.

A later filed copending patent application has a claim that reads as follows:

Application Claim 1: A device comprising the combination of elements A, B, C, and Y.

This application claim was never earlier presented. The combination ABCY is not considered obvious over the combination ABCX.

DISCUSSION

This is not a case of an improvement or modification invented after filing. Applicant in the application is claiming an embodiment disclosed but never claimed in the patent - an option exercised by applicant, not as a result of a restriction requirement.

The rule against double patenting seeks to prevent the unjustified extension of the right to exclude granted by a patent beyond the 17 year term of a patent.

Thus, the question to be answered in this Example is whether or not the subject matter covered by the claim of the patent would have its 17 year term extended if the claim in the application is patented.

The double patenting determination involves two inquiries. First, is the same invention claimed twice (35 USC 101)?

Clearly, the answer is no.

As stated above, the invention claimed in the application is not considered obvious over the invention claimed in the patent. In making the analysis for non-statutory double patenting when it is of the non-obviousness variety, the First Question is: Is the subject matter recited in the claims of the application fully disclosed in the patent and covered by a claim in the patent? If the answer is no - double patenting does not exist.

If the answer is yes, the Second Question is: Is there any reason why applicant was prevented from presenting the same claims for examination in the issued patent? If the answer is no - a double patenting rejection is appropriate.

Applying this analysis, we find the answer to Question 1 to be yes.

The answer is yes because the transitional phrase "comprising" does not exclude the presence of elements other than A, B, C, X in the claim. Because of the phrase "comprising" the

patent claims not only provides protection to ABCX but also extends patent coverage to the disclosed combination - ABCXY. Likewise, if allowed, the claim of the application, because of the phrase "comprising", not only would provide patent protection to the claimed combination ABCY but would also extend patent coverage to the combination ABCXY - already disclosed and covered by the claim in the patent. Thus, the controlling fact is that patent protection for the device, fully disclosed in and covered by the claims of the patent, would be extended by the allowance of the claim in the application.

Since no reason is seen why applicant did not present the claim to ABCY, a double patenting rejection is appropriate.

Would double patenting exist if the patent claim read "... consisting of ... A, B, C, and X".

No. The "consisting" type language would not extend coverage to ABCXY or ABCY. Consisting is a transitional phrase which limits the scope of the claim to only those elements set forth in the claim.

PROPOSED FORM PARAGRAPH STATEMENT PRIOR TO A D.P. REJECTION

The following non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. In re Sarett, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964); In re Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); In re White, 405 F.2d 904, 160 USPQ 644 (CCPA)

1969); In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

PROPOSED REJECTION IN SCHNELLER CASE

Claim 1 is rejected under the judicially created doctrine of double patenting.

The subject matter recited in claim 1 of the patent application - "comprising ABCY" - is fully disclosed in the patent. The allowance of this claim would extend the rights to exclude already granted in claim 1 of the patent - that right to exclude covering the device "comprising ABCX". The transitional phrase "comprising" does not exclude the presence of elements other than A, B, C, X in the claim. Because of the phrase "comprising" the patent claim not only provides protection to ABCX but also extends patent coverage to the disclosed combination - ABCXY. Likewise, if allowed, the claim of the application, because of the phrase comprising, not only would provide patent protection to the claimed combination ABCY but would also extend patent coverage to the combination ABCXY -

~~already disclosed and covered by the claim in the patent. Thus,
the controlling fact is that patent protection for the device,
fully disclosed in and covered by the claims of the patent, would
be extended by the allowance of the claims in the application.~~

~~Furthermore, there is no apparent reason why applicant was
prevented from presenting the claim in the application for
examination during the prosecution of the issued patent.~~